

Serial No.: 10/538,395  
Case No.: 21261P  
Page No.: 17

### REMARKS

Reconsideration of the present application as amended is respectfully requested.

Claims 1 to 21 and 28 to 38 were pending in the present application and subject to restriction.

Claims 1 to 21 and 28 to 38 have been canceled and new Claims 39 to 64 have been added.

### STATUS OF AMENDMENTS

The Claims have been amended in primarily two ways: (1) the compound claims have been replaced with claims directed to the composition comprising the corresponding compound of structural formula I and a pharmaceutically acceptable carrier; and (2) within structural formula I, R<sup>5</sup> and R<sup>6</sup> have been amended in accordance with the restriction requirement. These amendments are made without prejudice to filing a divisional application directed to the deleted subject matter

Support for pharmaceutical composition claims is found in the specification and claims as originally filed, for example at page 3, lines 25-26, and in original Claim 21.

The content and support for new Claims 39-64 is described in detail below.

New Claim 39 is an independent composition claim comprising a compound of structural formula I and a pharmaceutically acceptable carrier. The definitions of R<sup>5</sup> and R<sup>6</sup> in the compound of structural formula I have been amended by deletion of elements from Markush groups in response to the requirement for restriction. This has been done without prejudice to filing a divisional application directed to the deleted subject matter.

New Claims 40 to 47 are dependent claims directed to compositions comprising a compound of structural formula I incorporating the limitations to the compound of structural formula I of Claims 2-9.

New Claim 48 is dependent composition claim wherein in the compound of structural formula I, R<sup>6</sup> is hydroxy. New Claim 49 is also a dependent composition claim wherein in the compound of structural formula I, R<sup>5</sup> has been amended to delete -OR<sup>d</sup> and -NR<sup>c</sup>R<sup>d</sup> from original Claim 11. These amendments deleted elements from the Markush group corresponding to R<sup>6</sup> to comply with the restriction requirement.

New Claims 50 and 51 are dependent composition claims incorporating the limitations of original Claims 12, and 13, respectively in the definition of the compound of structural formula I.

New Claim 52 is a dependent composition claim comprising particular compounds of structural formula I. Support for these compounds is found in the specification at page 12, lines 16-36, and Examples 8 and 9 on pages 61 and 62.

Serial No.: 10/538,395  
Case No.: 21261P  
Page No.: 18

New Claim 53 is a method of treatment claim similar to original Claim 15 which has been amended to stand in independent form and sets forth the compound of structural formula I as restricted by the present restriction requirement. This has been done without prejudice to filing a divisional application directed to the deleted subject matter.

New Claims 54 to 62 are dependent method claims which depend directly or indirectly from Claim 53 and find support in original Claims 16 to 19 and previously presented Claims 32 to 36, respectively. In particular, Claims 58 to 62 find support in original Claims 15-19, and in the specification at page 3, lines 7 to 26; page 12, lines 16 to 36; and Examples 8 and 9 on pages 61-62.

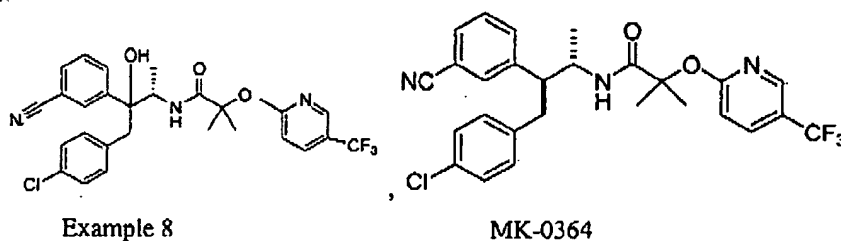
New Claim 63 is a prevention of obesity claim and claim similar to original Claim 20 which has been amended to stand in independent form and sets forth the compound of structural formula I as restricted by the present restriction requirement. This has been done without prejudice to filing a divisional application directed to the deleted subject matter.

New Claim 64 is a dependent claim identical in scope with previously presented Claim 38. Support for this claim is also found in Example 8, page 60, in the structure under line 26, and in the specification at page 3, lines 25-26.

Applicants submit that these amendments do not add new matter to the present application.

#### DISCLOSURE OF INFORMATION

The compound of Example 8, claimed in Claim 64, is an active metabolite of MK-0364, disclosed in



WO 03/077847, which has granted as US 6,972,295. Applicants believe that the 2-hydroxy compounds ( $R^6 = -OH$ ) of the present invention may be formed by in vivo metabolism of the corresponding 2-hydrogen compounds ( $R^6 = H$ ), disclosed in WO 03/077847.

#### RESTRICTION/ELECTION OF SPECIES

The Examiner required restriction is required under 35 USC §§ 121 and 372, stating that the present application contains the following fourteen inventions or groups of invention which the

Serial No.: 10/538,395  
Case No.: 21261P  
Page No.: 19

Examiner found to be not so linked as to form a single general inventive concept under PCT Rule 13.1.

The Examiner presented the following groups:

Group I: Claims 1-14, 21, 28-31, 37-38, drawn to a compound of formula (I) where  $R^5$  is attached to the amide group by a carbon atom and  $R^6$  is alkyl, alkenyl, alkynyl, halogen, or CN.

Group II: Claims 1-14, 21, 28-31, 37-38, drawn to a compound of formula (I) where  $R^5$  is attached to the amide group by an oxygen atom and  $R^6$  is alkyl, alkenyl, alkynyl, halogen, or CN.

Group III: Claims 1-14, 21, 28-31, 37-38, drawn to a compound of formula (I) where  $R^5$  is attached to the amide group by a sulfur atom.

Group IV: Claims 1-14, 21, 28-31, 37-38, drawn to a compound of formula (I) where  $R^5$  is attached to the amide group by a nitrogen atom and  $R^6$  is alkyl, alkenyl, alkynyl, halogen, or CN.

Group V: Claims 1-14, 21, 28-31, 37-38, drawn to a compound of formula (I) where  $R^5$  is attached to the amide group by a carbon atom and  $R^6$  is  $OR^d$  or  $-NR^dR^c$ .

Group VI: Claims 1-14, 21, 28-31, 37-38, drawn to a compound of formula (I) where  $R^5$  is attached to the amide group by an oxygen atom and  $R^6$  is  $OR^d$  or  $-NR^dR^c$ .

Group VII: Claims 1-14, 21, 28-31, 37-38, drawn to a compound of formula (I) where  $R^5$  is attached to the amide group by a nitrogen atom and  $R^6$  is  $OR^d$  or  $-NR^dR^c$ .

Group VIII: Claims 15-20 and 32-36 (in part), drawn to a method of treating a disease using the compound of Group I.

Group IX: Claims 15-20 and 32-36 (in part), drawn to a method of treating a disease using the compound of Group II.

Group X: Claims 15-20 and 32-36 (in part), drawn to a method of treating a disease using the compound of Group III.

Group XI: Claims 15-20 and 32-36 (in part), drawn to a method of treating a disease using the compound of Group IV.

Group XII: Claims 15-20 and 32-36 (in part), drawn to a method of treating a disease using the compound of Group V.

Group XIII: Claims 15-20 and 32-36 (in part), drawn to a method of treating a disease using the compound of Group VI.

Group XIV: Claims 15-20 and 32-36 (in part), drawn to a method of treating a disease using the compound of Group VII.

The Examiner stated that the inventions listed as Groups I - XIV did not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lacked the same

Serial No.: 10/538,395  
Case No.: 21261P  
Page No.: 20

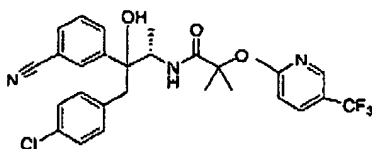
or corresponding special technical features for the following reasons: the corresponding technical feature between the inventions is the core structure of the compound of formula I. The Examiner stated that the structure comprises an amide and an *N*-ethyl substituent wherein the *N*-ethyl substituents is *b*-substituted by two aryl groups, or two heteroaryl groups, or one aryl the other heteroaryl groups. The Examiner further stated that the corresponding technical feature based on the core structure of the compound of formula (I) does not constitute a special technical feature over the prior art, particularly Canonica et al. [Gazzetta Chimica Italiana (1954), 84, pp. 175-186.].

The Examiner stated that he had required restriction between product and process claims and was open to rejoinder of withdrawn process claims depending from or otherwise requiring all the limitations of the allowable product claims. Applicants believe that the Examiner was referring to product and method of treatment claims.

The Examiner also required an election of species for examination.

Applicants elect the claims corresponding to Group V, Claims 1-14, 21, 28-31, 37-38, presently roughly corresponding to new Claims 39-52, and 64, drawn to a composition comprising compound of formula (I) where  $R^5$  is attached to the amide group by a carbon atom and  $R^6$  is  $OR^d$  or  $NR^dR^e$ , with traverse. Applicants respectfully submit that Group V should be rejoined with Group XII (current Claims 53-63), which are method of treatment/prevention claims, employing a compound of structural formula I wherein  $R^5$  is attached to the amide group by a carbon atom and  $R^6$  is  $OR^d$  or  $NR^dR^e$ .

Further, Applicants elect the compound of Example 8 and Claim 64, namely *N*-{[3-(4-chlorophenyl)-2-(3-cyanophenyl)-2-hydroxy-1(*S*)-methyl]propyl}-2-(5-trifluoromethyl-2-pyridyloxy)-2-methylpropanamide:



as the species for examination. New Claims 39-64 are all readable on the elected species.

MPEP 803.02 specifically acknowledges that even though a Markush claim includes independent and distinct inventions, the Examiner is required to extend the search of the Markush-type claim for patentability beyond the examination of the elected species where no prior art is found that anticipates or renders obvious the elected species. Toward this end, the Examiner may require a provisional election of a single species prior to examination on the merits. Following election, the Examiner must examine the Markush-type claim fully with respect to the elected species, and further

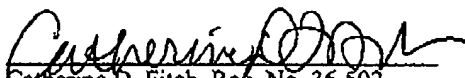
Serial No.: 10/538,395  
Case No.: 21261P  
Page No.: 21

to the extent necessary to determine patentability. Applicants understand that upon the allowance of a generic claim, they will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR §1.141.

Applicants respectfully submit that the application is allowable, and a favorable response from the Examiner is earnestly solicited.

Respectfully submitted,

By

  
Catherine D. Fitch, Reg. No. 36,502  
Attorney for Applicants

/agb

January 11, 2007

MERCK & CO., Inc.  
P.O. Box 2000  
Rahway, New Jersey 07065-0907  
Tel: (732)594-4283